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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/806,972 Confirmation No. 2337  
Applicant : Donovan  
Filed : March 22, 2004  
Title : BOTULINUM TOXIN THERAPY FOR NEUROPSYCHIATRIC  
DISORDERS

TC/A.U. : 1600/1645  
Examiner : Portner, V.A.

Docket No. : 17500CON(BOT); D3170-CON  
Customer No. : 33197

## CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted via facsimile to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, to fax number 703-872-9306, on the date indicated below.

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 6, 2005  
Frank Uxa

LETTER TRANSMITTING TERMINAL DISCLAIMER

Dear Sir:

Submitted herewith is a Terminal Disclaimer in the above-identified application. The Commissioner is hereby authorized to charge the necessary fee of \$130.00 (37 CFR 1.20(d)) to Deposit Account No. 01-0885.

Respectfully submitted,



Frank Uxa  
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Jun-03-05 03:26pm From-ALLERGAN LEGAL DEPARTMENT

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T-590 P.02/04 F-879

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Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 6, 2005  
Maet McAllee

TERMINAL DISCLAIMER

Sir:

Your petitioner, Allergan, Inc., having a place of business at 2525 Dupont Drive, Irvine, California 92612, by its attorney, Stephen Donovan, of record in the above-identified application, represents that it is the assignee, as shown by the assignment recorded in the Patent and Trademark Office on April 7, 2003, at Reel 013898, Frame 0170, of the entire right, title and interest in and to the above-identified application.

Pursuant to 37 CFR 3.73(b), your petitioner, as assignee of the above-identified application, hereby states that the above-noted assignment, the evidentiary document on which ownership of the above-identified application is established, has been reviewed. Further, your petitioner hereby certifies that, to the best of your petitioner's knowledge and belief, title to the

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T-590 P.03/04 F-879

Appl. No. 10/806,972  
Terminal Disclaimer

2

above-identified application is in your petitioner, as assignee seeking to take the action in this Terminal Disclaimer.

Your petitioner, Allergan, Inc., hereby disclaims the terminal part of any United States patent granted on the above-identified application which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from United States Application No. 10/421,504 and of United States Patent Nos. 6,620,415; 6,372,226; 6,333,037; and 6,306,403, and hereby agrees that any United States patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to such patent shall be the same as the legal title to any patent issuing from United States Application No. 10/421,504 and of United States Patent Nos. 6,620,415; 6,372,226; 6,333,037; and 6,306,403, this agreement to run with any patent granted on the above-identified application and be binding upon the grantee, its successors or assigns.

Petitioner does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from United States Application No. 10/421,504 and of United States Patent Nos. 6,620,415; 6,372,226; 6,333,037; and 6,306,403 in the event that one or more later expire for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321(a), has all claims canceled by a reexamination certificate, or is otherwise terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Jun-09-05 03:27pm From-ALLERGAN LEGAL DEPARTMENT

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T-590 P.04/04 F-879


Appl. No. 10/806,972  
Terminal Disclaimer

3

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 3<sup>rd</sup> day of June, 2005.

Respectfully submitted,

  
Stephen Donovan,  
Attorney of Record  
Reg. No. 33,433

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Appl. No. 10/806,972  
Reply to Office Action of February 8, 2005

19. (Original) The method of claim 17, wherein the neuropsychiatric disorder is selected from the group consisting of schizophrenia, Alzheimer's disease, mania, and anxiety.

20. (Currently amended) A method for treating a neuropsychiatric disorder, the method comprising a step of administering to a patient with a symptom of a neuropsychiatric disorder a therapeutically effective, non-lethal amount of a botulinum toxin, wherein the botulinum toxin is locally administered to ~~neural tissue at an intracranial site~~ a site of the brain located within the skull of the patient which is associated with the symptom of the neuropsychiatric disorder, thereby treating the symptom of the neuropsychiatric disorder by reducing neurotransmitter release from neurons contributing to the symptom of the neuropsychiatric disorder within about four months after the administration of the botulinum toxin.

21. (Currently amended) A method for treating schizophrenia, the method comprising a step of administering to a patient with schizophrenia a therapeutically effective, non-lethal amount of a botulinum toxin, wherein the botulinum toxin is locally administered to ~~neural tissue at an intracranial site~~ a site of the brain located within the skull of the patient which is associated with a symptom of schizophrenia, thereby treating schizophrenia.

22. (Original) The method of claim 21, wherein the botulinum toxin is botulinum toxin type A

23. (Cancelled)

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Remarks

Introduction

The above-identified application has been carefully reviewed in light of the Office Action mailed February 8, 2005, which included a final rejection of the pending claims. Applicant submits that the amendments and remarks included herein show the present claims to be allowable and do not raise new issues. For example, applicant submits that the amendments to the claims relate to subject matter already being examined, including the subject matter that includes claims 8 and 9. Therefore, applicant respectfully requests that this amendment be entered.

Claims 1-22 were pending. By way of this response, claims 1, 8, 9, 11, 17, 20, and 21 have been amended. Independent claims 1, 17, 20, and 21 have been amended to make more clear that the site at which the neurotoxin administered is a site of the brain, which is located within the skull of the patient and which is associated with the symptom of the disorder being treated. Claims 8, 9, and 11 have been amended to read more clearly in view of the language claim 1. Support for the amendments to the claims can be found in the application as originally filed, such as at page 23, lines 16-17. Care has been taken to avoid adding new matter. Accordingly, claims 1-22 remain pending.

Obviousness-type Double Patenting

Claims 1-5, 7-12, 17-18, and 20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3 and 5-12 of U.S.